Results: A total of 18 pts were treated. All had prior platinum and 16 pts had prior taxanes; 15 were platinum-refractory (i.e., progressed on treatment or within 3 months after treatment) and 14 were taxane-refractory. The first group of 12 pts were randomized; 6 each to Arm A and Arm B. Toxicity was mild to moderate. In Arm A (docetaxel 75 mg/m^2 + suramin), 3 pts had neutropenic fevers. Therefore, the docetaxel dose was reduced by 25%, and 6 additional pts were treated with 56 mg/m^2 docetaxel + suramin. No febrile neutropenia was observed at the lower docetaxel dose or for pts treated with gemcitabine + suramin. Among the 18 pts, 4 received only gemcitabine + suramin, and 14 received docetaxel + suramin (with or without rotating to gemcitabine + suramin). Pharmacokinetic analysis revealed that the plasma suramin concentrations were <50 μM in all of the treatments and were >10 μM in 87% of all treatments. The following table summarizes the response and survival data. The group that received docetaxel + suramin appeared to have more favorable response and survival compared to the group that received only gemcitabine + suramin.

Group (n)	% platinum-refractory	% taxane-refractory	Median # of cycles	Best response, %			PFS Months	MST, Months (95% CI)	1 yr survival %
				PD	ORR	SD			
Sur + Gem only (4)	100	75	2.5	50.0	0.0383	50.0	3.2 (1.9, 5.3)	4.1 (2.0, 6.9)	
Sur + Doc (5) & Sur + Doc/Gem (9)	79	79	5	23.1	15.4	61.5	4.0 (2.4, 5.3)	11.8 (5.4, 14.0)	50.0
Overall (18)	83	78	3.5	27.8	11.1	61.1	3.9 (2.4, 5.0)	9.1 (4.1, 12.7)	38.9

Conclusions: Combinations of nontoxic suramin with docetaxel 56 mg/m^2 or gemcitabine 1250 mg/m^2 is well tolerated. Suramin + docetaxel (56 mg/m^2) may have activity in paclitaxel/platinum-pretreated/refractory NSCLC patients. Supported in part by NCI UOlCA76576 and Sanofi-Aventis.

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Palliative Chemotherapy for Pulmonary Pleomorphic Carcinoma

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Background: Pulmonary pleomorphic carcinoma is a rare tumor of the lung which is believed to spread at an early stage and to have an aggressive clinical course. The efficacy of chemotherapy for advanced pulmonary pleomorphic carcinoma has not been defined. The objective of this study was to evaluate the efficacy of palliative chemotherapy for pulmonary pleomorphic carcinoma.

Methods: Thirteen consecutive patients who received palliative chemotherapy for advanced pulmonary pleomorphic carcinoma were investigated. All 13 patients were treated using chemotherapy regimens known to be active for the treatment of advanced non-small cell lung cancer (NSCLC).

Results: Of 13 patients, Nine were male (78.8%) and four were female (21.2%), and median age was 59 years with a range of 50 to 77 years. Eleven patients (85%) had progressive disease and two (15%) had stable disease after first-line chemotherapy. No patient achieved an objective response (objective response rate, 0%; 95% confidence interval, 0-23%). Eight of thirteen patients were given second-line chemotherapy, and all had progressive disease after second-line chemotherapy (objective response rate, 0%; 95% CI, 0-32%). Median overall survival from the initiation of first-line palliative chemotherapy was only 4 months (range, 2-12) with a median follow up of 16 months.

Conclusion: Advanced pulmonary pleomorphic carcinoma showed poor response to chemotherapy regimens that provide active treatment for NSCLC. Novel treatment approaches are required for pulmonary pleomorphic carcinoma.

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Phase II study of weekly paclitaxel plus carboplatin combination chemotherapy in patients with advanced non-small cell lung cancer

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Background: A weekly administration of paclitaxel has demonstrated a sustained efficacy and more favorable toxicity profile than a 3-weekly administration. The present study was conducted to evaluate the efficacy and safety of a combination regimen of weekly paclitaxel plus carboplatin in patients with advanced non small cell lung cancer (NSCLC). In addition, we examined 6 polymorphism of ERCC1, XPD and XRCC1 and whether these polymorphism have an effect on response and survival in advanced NSCLC patients who have received this regimen.

Methods: Patients with previously untreated measurable advanced NSCLC received intravenous paclitaxel 90 mg/m^2 on days 1 and 8 plus carboplatin AUC 6 on day 1 based on a 3-week cycle. We used polymerase chain reaction-restriction fragment length polymorphism to evaluate genetic polymorphism of the ERCC1 (Asn118Asn, Asp312Asn), XPD (Asp312Aap, Lys751Gln) and XRCC1 (Arg194Trp, Arg280His, Arg399Gln).

Results: From August 2005 to date, 32 patients were enrolled in this study. An overall response rate was 43.7%. The estimated median time to progression and median overall survival was 5.4 months and 11.3 months, respectively. Grade 3 neutropenia occurred in 7 patients, grade 4 neutropenia in 2 patients and febrile neutropenia was observed in 1 patient. Non hematologic toxicities were mild. There were no treatment-related deaths. There was no relationship between polymorphisms of DNA repair gene and response rate.

Conclusions: A weekly paclitaxel and carboplatin combination was found to be well-tolerated and effective in patients with advanced NSCLC. Final data, including relationship between polymorphisms of DNA repair gene and survival, will be presented at the meeting.